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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/684,215 | 10/06/2000 | Yasir Skeiky | 14058-008010US | 2519 |

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EXAMINER

LIU, SAMUEL W

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1653 | (10) |

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|--|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/684,215 | SKEIKY ET AL. |
| Period for Reply | Examiner | Art Unit |
| | Samuel W Liu | 1653 |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>one</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status | | |
| 1) <input type="checkbox"/> Responsive to communication(s) filed on _____. | | |
| 2a) <input type="checkbox"/> This action is FINAL . 2b) <input checked="" type="checkbox"/> This action is non-final. | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-31</u> is/are pending in the application. | | |
| 4a) Of the above claim(s) <u>none</u> is/are withdrawn from consideration. | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | |
| 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | |
| 8) <input checked="" type="checkbox"/> Claim(s) <u>1-31</u> are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. | | |
| If approved, corrected drawings are required in reply to this Office action. | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | |
| 13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | |
| a) <input type="checkbox"/> All* b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: | | |
| 1. <input type="checkbox"/> Certified copies of the priority documents have been received. | | |
| 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. | | |
| 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | |
| 14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | |
| a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | |
| 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | |
| Attachment(s) | | |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | | |
| 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. | | |
| 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | | |
| 6) <input type="checkbox"/> Other: _____. | | |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16 and 27-29 and 31, drawn to polynucleotide and expression of the transferred polynucleotide in a host cell, classified in class 536, subclass 23.1 and class 435, subclass 69.1, 455 and 320.1.
- II. Claims 17-26, drawn to fusion polypeptide, classified in class 424, subclass 192.1.
- III. Claim 30, drawn to method of cleaving the fusion polypeptide, classified in class 435, subclass 68.1.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Invention II are patentably distinct from each other because of the materially different structures of the compounds claimed. The Invention I is drawn to a polynucleotide, while Invention II is drawn to fusion polypeptide. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotide that is classified in class 536, subclass 23.1, and/or to an expression vector in which the polynucleotide directs synthesis of gene products, where directed to polynucleotide molecules being transformed into a host microorganism, which process would have been searched in class 435 subclass 69.1.

Invention I (polynucleotide) and Invention III (a method of cleavage of the fusion polypeptide) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed

as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mode of operation for inventions I and III are different. Invention I claims a product, a polynucleotide, that requires a different process for its making and using than Invention III in which different products is used in different process i.e. enzymatically cleaved fusion polypeptide is structurally distinct from uncleaved one. Furthermore, Invention I requires biosynthesis machinery whereas Invention III required a mechanism of enzymatically cleaving product of Invention I, i.e. the fusion polypeptide. Thus, the mode of operation as well as function of the end products for Invention I and III are different.

Invention II (fusion polypeptide) and Invention III (a method of cleavage of the fusion polypeptide) are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the fusion polypeptide can be utilized in a materially different process, producing an antibody that specifically recognizes and binds to the fusion polypeptide, for example.

Because reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Annette Parent on May 7, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

Christopher S. Low
CHRISTOPHER S. P. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

May 14, 2002